Exhibit B

Part II

not have performed the patented process itself. See Pfizer Inc. v. Aceto Corp., 853 F. Supp. 104, 106 (S.D.N.Y. 1994) (Lasker, J.) (corporation that imported, but did not manufacture, product made by patented process was nevertheless liable under Section 271(g)).[19]

Roche next argues that it is not liable under Section 271(g) because it was not the "importer" of the albumin-free EPO. Instead, it claims that GI imported the goods itself into the United States in order to administer it to the Jehovah's witness patients. This argument clearly fails. The evidence demonstrates that Roche shipped the albumin-free EPO to GI in the United States. Under the statute, the term "import" has its "plain ordinary meaning of bringing goods into the United States." Bristol-Myers Co. v. Erbamont Inc., 723 F. Supp. 1038, 1044 (D. Del. 1989). Because the albumin-free EPO was made using a patented process,[20] Roche is liable under Section 271(g) for shipping these goods to GI in the United States.

To the extent that Roche is arguing that it cannot be held liable under the statute because it merely shipped the albumin-

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[19] The legislative history also makes clear that "the offending act is the importation of a product made through the use of a protected process patent or its subsequent sale in the United States." H.R. Rep. No. 60, 100th Cong., 1st Sess. 6 (1987) (emphasis added).

[20] Whether GI created the product by utilizing a process patented by the Axel patents was discussed in Section III(A)(1)(b)-(c), supra.

free EPO to GI in the United States, and neither Roche nor GI sold the product, this argument founders on the plain language of the statute. Under Section 271(g), liability attaches to one who "imports into . . . or . . . sells . . . within the United States a product which is made by a process patented in the United States." (Emphasis added). While selling the product within the United States is an alternative ground for violating the statute, merely importing the offending product into the United States is a sufficient basis to impose liability. Thus, because these cells were made using a process patented by Columbia,[21] Roche is liable under Section 271(g) for shipping these goods to GI in the United States.

b. Importing GI's "Bailed" Cells

In early March 1989, Roche returned a number of so-called "bailed" vials of MWCB to GI in the United States at GI's request. To defend against Columbia's claim of liability, in addition to the same failed arguments that it raised in the albumin-free EPO context, Roche argues that it cannot be held liable under Section 271(g) because it never owned these "bailed" cells, which at all times remained the property of GI. It claims

[21] Whether GI created these MWCB cells by utilizing a process patented by the Axel patents was discussed in Section III(A)(1)(b)-(c), supra.

that it could not have "imported" these cells under Section 271(g), if it never owned the cells.

This argument again finds no support in the plain language of the statute or in the common meaning of the word "import," and not surprisingly, Roche cannot cite a single authority that supports its interpretation. Whether or not Roche owned the cells is irrelevant. It is undisputed that Roche shipped the cells into the United States, and thus imported them under the statute. See Bristol-Myers Co., 723 F. Supp. at 1044 (finding that "Congress did not intend the term 'importation' to turn upon extremely intricate concepts of title and sales contracts.") As a result, because these cells were made using a process patented by Columbia,[22] Roche is liable under Section 271(g) for shipping these goods to GI in the United States.

B. Roche's Defenses

Roche asserts numerous affirmative defenses to liability under Sections 271(b) or 271(g). It raises the defenses of obviousness, inequitable conduct, unclean hands and patent

[22] Whether GI created these MWCB cells by utilizing a process patented by the Axel patents was discussed in Section III(A)(1)(b)-(c), supra. I concluded that Roche did not induce the creation these cells in Section III(A)(2)(a), supra. However, Roche's importing these cells back into the United States creates an independent basis for liability, as described in Section III(A)(3).

misuse, possession of an implied license, and laches. I will address each of these in turn.

1. **Are Claims 54-73 Of The '216 Patent Invalid Because Of Obviousness?**

Roche argues that claims 54-73 of the '216 are invalid due to obviousness. In doing so, it argues that these claims, which involve linked cotransformation followed by subsequent amplification, would have been obvious to a person having ordinary skill in the art at the time the invention was made. However, Roche explicitly concedes that "it is not asserting that the claims of unlinked cotransformation are obvious." Roche's Post-Trial Memorandum at p. 20 (emphasis added).

Because a patent is presumed to be valid once it is issued by the PTO, Roche bears the burden of proving its defense of the invention's invalidity by clear and convincing evidence. 35 U.S.C. § 282; Greenwood v. Hattori Seiko Co., Ltd., 900 F.2d 238, 241 (Fed. Cir. 1990). Under 35 U.S.C. §103(a), a patent may not be obtained if its "subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art . . . ." In order to determine whether a patent would have been obvious at the time the invention was made to a person having ordinary skill in the art, the Supreme Court has instructed courts to examine the following four

factors: (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) objective evidence of non-obviousness, such as commercial success, long-felt but unsolved need, or the failure of others. Graham v. John Deere & Co., 383 U.S. 17-18 (1966); Greenwood, 900 F.2d at 241. I must also consider the obviousness of the claimed invention as a whole. Even if elements of the claimed invention viewed in isolation would be obvious, "[w]hat must be found to be obvious to defeat the patent is the claimed combination." Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed. Cir. 1990).

The objective secondary factors, for the most part, weigh heavily in Columbia's favor. Most significantly, the overwhelming commercial acquiescence by the pharmaceutical industry to the legitimacy of the Axel patents supports a finding of non-obviousness. See Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1575 (Fed. Cir. 1992); Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1270-71 (Fed. Cir. 1991) (holding that the significance of a new invention "is often better measured in the marketplace than in the courtroom.") Twenty-eight major pharmaceutical companies have paid for a license to the Axel patents, generating over hundreds of millions of dollars in

royalties for Columbia based upon billions of dollars in drug sales by these companies. That these companies were willing to part with such extraordinary sums is strong independent evidence that the Axel patents were not obvious.

Roche points to the prior art publications, specifically those of Nunberg, et al. (Trial Ex. D206) and Schimke, et al. (Trial Ex. D474) to argue that the claims of the Axel patents describing linked cotransformation followed by subsequent amplification would have been obvious.[23] While it does not claim that the linked cotransformation claims were obvious in light of either publication by itself, it suggests that it would have been obvious to a person having ordinary skill in the art to combine their teachings and conceive of the invention embodied in the Axel patents. To support this conclusion, Roche offers the expert opinion of its witness, Dr. Kaufman, who testified that the prior art had established that "when genes get amplified, they amplify a large piece of DNA. They amplify sequences that are adjacent to the gene. So, it becomes obvious that if the

[23] In addition, Roche points to Mantei, et al. Trial Ex. D108, which was cited to the PTO during the prosecution of the patents. The citation was withdrawn after the inventors filed a declaration under Rule 131, 37 C.F.R. § 1.131, noting that their invention was conceived and reduced to practice before Mantei's publication. Roche challenges this representation. See infra, III.B.

genes were linked, that they would amplify together." Trial Tr. 1299:24-1300:2.

Roche bolsters Dr. Kaufman's opinion by arguing that during the prosecution of the '665 patent, the PTO Examiner rejected claims based on linked cotransformation offered by Columbia because these claims were obvious in light of prior art publications by Willicke, et al. in view of publications by Nunberg, et al. The PTO did not reject the linked claims during the prosecution of the '216 patent, the only patent at issue here, Roche claims, because the Examiner was not aware of the Nunberg, et al. article at that time.

What Roche has not done is to offer any credible evidence concerning what the level of ordinary skill in the art was at the time of the invention. Graham, 383 U.S. at 17; see also Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir.1991) ("the level of ordinary skill in the art is a factual question that must be resolved and considered.") Dr. Kaufman offered his opinion that linked cotransformation would have been obvious to him at the time of the invention, but there is no evidence that

the skill level of Dr. Kaufman was the same as that of a person having ordinary skill in the art.[24]

Given its burden of proof, Roche's invalidity defense to claims 54-73 of the '216 patent fails.

2. Are Claims 54-73 of the '216 Patent Barred By Inequitable Conduct By Columbia?

Patent applicants have a duty to prosecute their patent applications in the PTO with good faith, candor, and honesty. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). Roche argues that inequitable conduct by Columbia's attorney John White during the prosecution of the Axel patents bars any recovery by Columbia for infringement. To prevail on this defense, Roche must prove by clear and convincing evidence that Columbia made affirmative misrepresentations of fact, submitted materially false evidence, or failed to disclose material information to the PTO and did so with an intention to deceive the PTO. Molins, 48 F.3d at 1178-81; Baxter Intern., Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1573-74 (Fed. Cir. 1991).

[24] Dr. Kaufman also acknowledged that he had not read the Court's Markman findings and thus could not relate his conclusions to the claims as construed.

Roche is not claiming that the inventors themselves lied to the PTO. Instead, it argues that Columbia attorney John White intentionally misrepresented statements contained in the declarations filed by the inventors pursuant to 37 C.F.R. § 1.131 ("Rule 131 declarations").[25]

Attorney White argued to the PTO that the Rule 131 declarations established that the inventors "actually reduced to practice claimed embodiments of their invention prior to the effective date of the Mantei et al. article (September 6, 1979) or the Lai et al. article (January 1980)." Trial Ex. P288 at 216-249 - 216-250 (emphasis added). Roche claims that White's representation that the Rule 131 declarations established that the invention was reduced to practice prior to the effective date of the Mantei et al. article was deliberately misleading because the declarations did not state that the subject matter of the linked claims were reduced to practice prior to the Mantei et al. article. In fact, while the inventors did declare that the

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[25] 37 C.F.R. § 1.131(a) states:

> When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim . . . may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.

37 C.F.R. § 1.131(a).

invention as a whole was reduced to practice prior to Mantei, they did not specifically state that the claims involving linked amplification followed by subsequent amplification (which later became claims 54-73 of the '216 patent) were reduced to practice prior to Mantei et al. Compare Trial Ex. P288 at 216-166 - 216-169, Trial Tr. 1579-1580 with Wigler Depo. at 94:16- 98:3, 171:1-173:7; Silverstein Depo. at 96, 98-100, 103. Roche argues that both the PTO and Mr. White believed that linked cotransformation was patentably distinct from unlinked cotransformation, so when White said that "the invention" was reduced to practice prior to Mantei et al., he made a material omission because the inventors had not reduced to practice the process described in claim 54-73 of the '216 patent relating to linked cotransformation prior to Mantei et al.

Roche's argument falls for several reasons. First, it is not at all clear that White made any material misrepresentations or omissions. By stating that the declarations established that the inventors of the Axel patents had reduced the invention to practice prior to the effective date of Mantei et al., he was accurately reporting what the inventors had stated in their declarations. Furthermore, Rule 131 requires that the applicant make an oath "to facts showing a completion 'of the invention.' That requirement does not mean [the] affiant must show a

reduction to practice of every embodiment of the invention." In re Hostettler, 356 F.2d 562, 565-66 (C.C.P.A. 1966). Finally, even if Columbia had been required to show a reduction to practice of the specific claims at issue, Roche had produced no evidence to support a finding of a specific intent to deceive the PTO by White. White clearly believed that evidence of a reduction to practice of the invention as a whole was sufficient to meet the PTO's concerns, and there is no evidence that he intentionally deceived the PTO.

As a result, Roche's inequitable conduct defense fails.

3. **Does Columbia Have Unclean Hands, or Did it Misuse its Patents with Anti-competitive Effect?**

Roche next argues that the Axel patents are unenforceable due to Columbia's unclean hands and patent misuse. It claims that Columbia's license of the Axel patents to Johnson & Johnson ("J&J") violated restrictions placed upon the patents by the National Institute of Health ("NIH") and unlawfully restricted competition in the EPO market for J&J's benefit.

A defense of unclean hands arises from the equitable maxim, "he who comes into equity must come with clean hands." It prevents one who is "tainted with inequitableness or bad faith relative to matter in which he seeks relief" from obtaining

relief from a court of equity. Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 816 (1945).

A party asserting the affirmative defense of patent misuse must prove that the patent owner has "impermissibly broadened the scope of the patent grant with anticompetitive effect." C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998), cert. denied, 526 U.S. 1130 (1999). The patent misuse defense is available even if the infringer has not suffered personally from the misuse of the patent. Morton Salt Co. v. G.S. Suppinger Co., 314 U.S. 488, 494 (1942).

Certain actions constitute per se patent misuse, including (1) requiring the purchase of unpatented goods for use with patented apparatus or processes ("tying"); (2) prohibiting production or sale of competing goods; and (3) conditioning the grant of a license under one patent upon acceptance of another and different license. See Donald S. Chisum, 6 Chisum on Patents, § 19.04[3] at 19-451 (2002). "Anticompetitive effects that are not per se violations of law are reviewed in accordance with the rule of reason. Patent owners should not be in a worse position by virtue of the patent right to exclude, than owners of other property used in trade." Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 708 (Fed. Cir. 1992). Under the rule of reason, I must "decide whether the questioned practice imposes an

unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997).

In 1980, Columbia filed a "Petition for Determination" with NIH to request approval of the assignment of the invention to Columbia and of its plan to license the invention to third parties for development. NIH had funded the research that produced the patents, and seeking that approval was a requirement if Columbia wanted to commercialize an invention made with federal funds. Sgarlat Depo. 34:15-20. NIH responded by letter in February 1981 (the "NIH Determination letter") and denied Columbia's request to grant it an exclusive license. The letter allowed Columbia to license the invention non-exclusively, subject to conditions, including 1) every license "shall include adequate safeguards against unreasonable royalties and excessive trade practices," and 2) Columbia must not grant any exclusive license for a period longer than five years without the approval of NIH. Trial Ex. D315.

In 1989, Columbia granted a license to J&J which granted J&J "exclusive" rights to use the Axel patents in the making, using,

and selling of EPO. Trial Ex. P257 at 2-3. However, that license recognized that twelve other companies had been previously licensed to use the Axel patents in the making, selling, and using of EPO and that they would continue to be able to do so. It also contained a provision where J&J was required to issue a sublicense to four other companies (including GI and Roche) upon their request, provided that these companies would agree not to assert a patent infringement claim against J&J based on J&J's making, selling, or using EPO. Id. Columbia also reserved all rights required to be granted to the U.S. Government. Id.

Roche argues first that Columbia is guilty of unclean hands because the 1989 license to J&J violated the terms of the NIH Determination letter. Roche claims that Columbia violated the NIH Conditions by (1) not submitting the 1989 "exclusive" license to J&J to NIH for approval; (2) granting J&J exclusivity over using the Axel patents for making, using, and selling EPO for over eleven years even though the Determination Letter limited the duration of any exclusive license to five years; and (3) making abandoning a right to sue J&J for patent infringement a condition of J&J's granting of a sublicense to four companies (including Roche and GI) because this condition was an "excessive

trade practice" in violation of the NIH Determination letter's ban of such practices.

However, the license that Columbia granted to J&J in 1989, although labelled an "exclusive" license, was not truly exclusive. It explicitly provided that twelve companies that had previously granted a license to make, use, or sell EPO under the Axel patents could continue to do so. It also included a provision which required J&J to sublicense four additional companies (including Roche and GI), provided that these companies agreed to drop any infringement claim against J&J based upon J&J's manufacture, use, or sale of EPO. Therefore, the license was not truly exclusive, and the fact that Columbia did not send this license with J&J to the NIH for approval does not make it guilty of unclean hands.

Roche further claims that independent of whether Columbia violated the terms of the NIH Determination letter, Columbia is guilty of patent misuse because its 1989 license to J&J wrongfully restricted competition in the EPO market for J&J's benefit. Roche argues that the clause in the 1989 license stating that J&J only needed to issue a sublicense to Roche and GI if they dropped any EPO patent infringement suit against J&J was a "suicide clause" because if Roche had agreed to this provision, it would have been effectively forced out of the EPO

market. Trial Tr. 1111-12. Roche says that this is per se patent infringement because it is analogous to a non-competition clause in the sale of EPO. They also argue that even if per se patent misuse does not apply, under the rule of reason, Columbia attempted to impermissibly broaden the scope of the Axel patents with anti-competitive effect.

The argument that Columbia engaged in predatory licensing practices does not pass muster. Roche was offered an opportunity to purchase a license to the Axel patents in 1984, without any restrictions about relinquishing its infringement claims against J&J. It refused to take such a license. Furthermore, Roche has failed to prove that an anti-competitive effect in the United States resulted from Columbia's licensing practices. Columbia correctly notes that Columbia licensed the Axel patents to dozens of companies. Its license to J&J even provided that J&J would sublicense the patents to Roche and GI if these companies agreed to drop certain patent infringement claims against J&J. Although Roche understandably might not have wished to give up an infringement claim against J&J in order to receive a sublicense to produce EPO under the Axel patents, it has failed to show an

anti-competitive effect on the market as a whole or even to provide any evidence defining any relevant market.[26]

As a result, Roche's defenses of unclean hands and patent misuse fail.

4. Did Columbia Grant An Implied License To GI And Roche?

Roche next argues that its conduct did not infringe the Axel patents because Columbia granted an implied license to use these patents to both GI and Roche. There is a two-pronged test for determining whether an implied license has been granted: "First, the equipment involved must have no noninfringing uses . . . . Second, the circumstances of the sale must plainly indicate that the grant of a license should be inferred." Met-Coil Systems Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 686 (Fed. Cir. 1986). The alleged infringer bears the burden of showing the establishment of an implied license. Id.; Bandag, Inc. v. Al Bosher's Tire Stores, Inc., 750 F.2d 903, 924 (Fed. Cir. 1984).

Roche's argument centers around a license granted by Lawrence and Gail Urlaub Chasin, professors at Columbia, to GI in 1984 (the "GI-Chasin license") to "make and use the Chinese

[26] Columbia points out that Roche stood in a different position vis a vis other Columbia licensees. It was a competitor who had asserted GI patents against J&J in Germany. Moreover, while the clause at issue restricted patent suits against J&J, it did not restrict patent suits against Amgen, the owner of J&J's patents.

hamster dihydrofolate reductase-deficient mutant cell lines" that they had isolated. Trial Ex. D227. The license stated that the authorization of Columbia had been obtained to grant the license to GI and that "[n]o right of . . . Columbia University . . . will be violated by the exercise of rights hereunder." Id. Roche also points to a substantially similar November 14, 1986, license from the Chasins to permit Roche to utilize the Chasins' cell lines to argue that Roche was granted an implied license as well.

Roche argues that the Chasin licenses created an implied license under the Axel patents because the DHFR-deficient CHO cell line that GI and Roche were licensed to use had no reasonable licensed use that did not infringe the Axel patents, and the circumstances surrounding the Chasin-GI license indicate that an implied license should be inferred.

What Roche fails to recognize is that the evidence suggested that the DHFR-deficient CHO cell line did have other reasonable uses that would not infringe the Axel patents. For instance, the DHFR-deficient CHO cell line could be used for general scientific research and study of the DHFR gene. Trial Tr. 576, 1336.

Roche argues that the fact that the cell line might have a reasonable non-infringing use as a tool for general scientific

research does not count for the purposes of the implied license analysis because general scientific research is not a commercial use of the cell line. Chasin testified that he generally did not require a license if someone wanted to use the cell line for non-commercial purposes. Chasin Depo. 15:12-21, 46:10-13. However, the fact that Dr. Chasin did not enforce his patent rights against those who might use his patented cell line without a license for general scientific research purposes does not change the fact that using the cell line for scientific research was a reasonable non-infringing use of the cell line. There is nothing in the case law that requires the reasonable non-infringing use to be of a commercial nature.

More importantly, the circumstances as a whole do not indicate that an implied license should be inferred. Columbia never gave any indication to Roche or GI that they had permission to use the Axel patents without an express license. In fact, although Columbia offered an express license to Roche in 1984 before GI received a license from Chasin, Roche refused that offer. Trial Ex. P273. In order to prove the granting of an implied license, Roche must prove a sale "by one with the authority of the patent owner." Donald S. Chisum, 5 Chisum On Patents 16.03[2][c] at 16-157 (2002). Even if Chasin represented that he had Columbia's authority to grant a license for

Columbia's Axel patents, he did not actually have the authority to do so. Even a minimum amount of due diligence by GI or Roche would have confirmed this fact. Chasin signed his license on his own behalf and not as an authorized representative of Columbia. Trial Ex. D227. Therefore, any assumption by Roche or GI that they had a license to use the Axel patents after receiving a license to utilize the Chasin's cell line was unreasonable.

GI's own actions also support the conclusion that GI did not receive an implied license to use the Axel patents from the GI-Chasin license. If GI had firmly believed that it possessed an implied license to use the Axel patents, it would not have purchased a license from Columbia to use the Axel patents to create products other than EPO and subsequently have paid millions of dollars to Columbia under the terms of the license. Trial Ex. P168; Trial Tr. 631.

Because the Chasin cell line had reasonable non-infringing uses and the surrounding circumstances do not indicate that an implied license should be granted, Roche's implied license defense fails.

5. **Are Columbia's Infringement Claims Barred By Laches?**

In order to assert the defense of laches, Roche must prove by a preponderance of the evidence: "(1) plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against defendant, and (2) the delay operated to the prejudice or injury of the defendant." A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1032 (Fed. Cir. 1992). Laches is presumed where the plaintiff delays filing suit for more than six years after the date the patentee knew or should have known of the infringer's activity. Id. at 1028. The patentee may then rebut this presumption by showing that the delay, in fact, was reasonable or that the defendant suffered no prejudice by the delay. The patentee also may be charged with constructive knowledge of the activity (even without actual knowledge) if the infringer's undiscovered activities are "sufficiently prevalent in the inventor's field of endeavor." Wanlass v. General Electric Co., 148 F.3d 1334, 1339 (Fed. Cir. 1998).

Roche argues that a series of events should have put Columbia on notice of its claims against Roche. Columbia filed its Complaint in the current action on July 12, 1993, almost ten years after the '216 patent was issued on August 16, 1983. Trial Ex. P1. Columbia sent a license solicitation to Roche in 1984,

which Roche refused. Trial Ex. P273. The GI-Roche D&L Agreement to produce EPO for commercial purposes was signed on October 8, 1985. However, there is no evidence in the record that GI or Roche made the fact of this agreement public. In fact, the agreement provided that neither party was permitted to produce "any publicity, news release or other public announcement, written or oral, relating to this Agreement, the Project or the existence of an arrangement between the parties without the prior written approval of the other Party . . . ." Trial Ex. P29 at ¶ 10.2.

In June 1986, GI's CHO-cell expression system that Columbia claims directly infringes the Axel patents was made public in GI's PCT patent application entitled "Method for the Production of Erythropoietin." Trial Ex. P169; Trial Tr. 536-541. However, Roche and its involvement are not mentioned anywhere in the patent application. According to the testimony of Eisen (former vice president and patent counsel for GI), it was "generally known" by 1986-87 that GI had a license with Roche for the EPO technology. Trial Tr. 705:12-18. However, Dr. Kaufman of GI stated that when he found out sometime in 1986 that Roche was working with his cells, he was quite surprised. Trial Tr. 1307.

In 1989, Dr. Silverstein of Columbia knew about GI's manufacture of bulk EPO but was not aware of any relationship

between Roche and GI. On February 2, 1989, a preliminary injunction hearing in the case of Amgen, Inc. v. Chugai Pharmaceutical Co. was held where GI's development of the EPO-production clone and manufacture of bulk EPO was addressed. However, it is unclear whether Roche's involvement was addressed at that hearing. On December 14, 1989, Columbia and J&J signed an agreement that Columbia had in its possession "substantial evidence of infringement" by GI. Trial Ex. P257. However, once again, this letter did not mention Roche. On November 20, 1990, Columbia filed suit against GI claiming that GI violated the Axel patents by making and selling EPO. Columbia decided to dismiss its lawsuit "without prejudice" against GI in June 1991. Trial Ex. D333.

By May 20, 1992, however, it is clear that Columbia had knowledge of Roche's activity with respect to EPO. On that date, Columbia sent a letter to Roche asking Roche to "take a sublicense with respect to your sales of EPO in Europe." Trial Ex. P90.

Roche argues that Columbia should have known about GI's production of EPO and its association with Roche back in 1986-1987 and that as a result, a presumption of laches should apply. This date is more than six years before Columbia filed its current lawsuit in 1993. However, the question of knowledge

properly relates to when Columbia was aware of Roche's involvement, not just GI's. One could not expect Columbia to sue Roche until it had reason to know that Roche had infringed Columbia's patents itself or had induced GI to infringe.

Although Eisen did testify that it was "generally known" that Roche had taken a license from GI with regard to its EPO production in 1986-87, the testimony of Dr. Kaufman and Dr. Silverstein, as well as the secrecy surrounding the Development and Licensing Agreement between Roche and GI, convinces me that Columbia was not aware, and should not have been aware, of Roche's activities at that time. The evidence establishing that Columbia knew about GI's relationship with Roche is quite thin before 1992.

Even if Columbia should have been aware of Roche's activities by 1989, a four year delay in filing suit would not be unreasonable under these circumstances. By November 1990, Columbia had filed suit against GI for patent infringement, and the Federal Circuit has held that existence of other litigation involving the same patent can excuse delays in filing suit. Auckerman, 960 F.2d at 1033; Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA, 944 F.2d 870, 876-77 (Fed. Cir. 1991). In this case, a delay by Columbia in filing suit against Roche until its litigation with GI had finished would be reasonable.

Nor has Roche shown material prejudice as a result of delay by Columbia. According to the Federal Circuit, "[e]conomic prejudice may arise where a defendant and possibly others will suffer the loss of monetary investments or incur damages which likely would have been prevented by earlier suit." Auckerman, 960 F.2d at 1033. Roche argues that it was prejudiced because between 1989 and 1991, it "continued to receive GI's shipments of bulk EPO without reason to believe that Columbia would attempt to enforce the U.S. Axel patents against such EPO." Roche's Post-Trial Memorandum at 37. However, to determine if the defendant has been prejudiced, "courts must look for a change in the economic position of the alleged infringer during the period of delay." Auckerman, 960 F.2d at 1033 (emphasis added). Having merely continued to receive the shipments of bulk EPO and not having changed its position, Roche cannot claim to have been prejudiced by Columbia's delay.

Because Columbia did not unreasonably delay in bringing its suit against Roche, and Roche was not materially prejudiced by any delay that did occur, Roche's defense of laches fails.

C. **Damages**

Because I have concluded that Roche has violated Section 271(b) and Section 271(g), and Columbia has prevailed on all of

Roche's affirmative defense, Columbia is entitled to damages as a result of Roche's infringement.

1. **Was Roche's Infringement Willful?**

Columbia argues that it is entitled to triple damages under 35 U.S.C. § 284 because Roche's infringement of the Axel patents was willful. Columbia must prove the willfulness of Roche's patent infringement by clear and convincing evidence. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1221 (Fed. Cir. 1995). There is no per se rule for determining willful infringement. The totality of the circumstances must be considered. Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 792 (Fed. Cir. 1995).

A potential infringer having actual notice of another's patent rights has an affirmative duty of due care which normally will entail the obtaining of competent legal advice before engaging in potentially infringing activity. Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft, 829 F.2d 1075, 1084 (Fed. Cir. 1987). Although the absence of an opinion of counsel is pertinent evidence in determining good faith, it is not dispositive. Rite-Hite Corp. v. Kelley Co., 819 F.2d 1120, 1125 (Fed. Cir. 1987); American Original Corp. v. Jenkins Food Corp., 774 F.2d 459, 465 (Fed. Cir. 1985). The primary focus of the

willfulness determination is the defendant's intent and reasonable beliefs. Ortho Pharmaceutical Corp. v. Smith, 959 F.2d 936, 944 (Fed. Cir. 1992); Stickle v. Heublein, Inc., 716 F.2d 1550, 1565 (Fed. Cir. 1983).

Columbia makes two arguments: First, it argues the infringement was willful because Roche never sought the advice of U.S. patent counsel concerning the making, using, and selling of GI's cell lines and EPO even though it knew about the Axel patents and had declined an opportunity to license the Patents in 1984. Instead, Roche relied solely on the opinion of its German in-house patent counsel, Dr. Fouquet, who believed it was not necessary to obtain an opinion from U.S. counsel. Trial Tr. 1142-1143.

Also, Columbia claims that a Roche employee's destruction of correspondence between GI and Roche relating to GI's manufacture of EPO after the lawsuit commenced was an effort to hide information which supports an inference against Roche on the question of willfulness. Trial Ex. D510. These documents, as well as thirty boxes of files relating to "dead" projects, according to the record, were discarded during a routine office move in February of 1995.

As such, Columbia has failed to carry its burden of proving Roche's willfulness by clear and convincing evidence. Roche's in-house counsel, Dr. Fouquet, determined that Roche did not need a license because Roche had no U.S. activities and believed that it had an implied license. Trial Tr. 1143:8-1146:13. Dr. Fouquet was the head of Roche's patent infringement division and had an understanding of U.S. patent law when he gave this opinion. While his opinion was incorrect, it was not an unreasonable interpretation of the facts as they applied to Roche.

In addition, the destruction of documents that Columbia trumpets cannot support a finding of willfulness. There is no evidence that these documents were destroyed in bad faith, and it does not in any way justify a finding of willful infringement by Roche.

2. **Columbia's Damages**

Because Columbia has proven that Roche infringed the Axel patents, it is entitled to damages under 35 U.S.C. § 284. 35 U.S.C. § 284 states:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer,

> together with interest and costs as fixed by the court.

Columbia argues that the "entire market value rule" entitles it to damages in the amount of "the entire market value of the benefit enjoyed by Roche." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1544-46 (Fed. Cir. 1995). The "entire market rule" typically allows the recovery of damages based on the entire value of an apparatus with several features, even though only one feature is patented. Paper Converting Machine Co. v. Magna-Graphics Corp., 745 F.2d 11, 22 (Fed. Cir. 1984). Columbia's argument is that Roche's inducing GI to provide it with the MCB, MWCB, and bulk EPO, made it possible for Roche to produce EPO in Europe, so Columbia ought to be able to recover any profits that Roche received from its sale of EPO in Europe. At the very least, Columbia argues that it is entitled to a reasonable royalty rate of 6% of net sales of EPO by Roche in Europe.

However, Columbia has incorrectly determined the relevant market for determining its damages. United States patent law permits no recovery for extraterritorial acts. See Johns Hopkins University v. CellPro, Inc., 152 F.3d 1342, 1367 (Fed. Cir. 1998) (If defendant's "infringement has damaged [plaintiff's] ability to service foreign markets, [plaintiff] must rely on foreign patent protection."); Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527-531 (1972) ("The statute [35 U.S.C. § 271] makes it

clear that it is not an infringement to make or use a patented product outside of the United States . . . . Our patent system makes no claim to extraterritorial effect.") Even though this Court has concluded that Roche is responsible for inducing GI to produce and sell bulk EPO, it is not responsible for subsequent acts that it may have taken outside of the U.S. border with respect to the bulk EPO thus obtained. Damages for foreign acts should be sought in foreign courts. John Hopkins University, 152 F.3d at 1367. Roche's liability is necessarily limited to damages which occurred in the United States, and does not extend to any subsequent use of the bulk EPO by Roche in Europe or sales of EPO developed from the bulk EPO.

However, while Columbia is entitled to a reasonable royalty rate from Roche's inducing GI to create bulk EPO to sell to Roche in Europe, the actual profits that Columbia lost due to Roche's infringement cannot be determined. Columbia does not, and has never attempted to, manufacture EPO. As such, Columbia's damages should be based on the construct of a reasonable royalty under the case law. Trell v. Marlee Electronics Corp., 912 F.2d 1443, 1445 (Fed. Cir. 1990).

This reasonable royalty may be based upon an established royalty, as Roche urges. Id. Columbia negotiated licenses to use the Axel patents with thirty-three companies. The

overwhelming majority of the licenses established a 3.0% royalty rate for bulk products. In 1989, Columbia did grant a license to J&J giving it "exclusive" rights to use the Axel patents in the making, using, and selling of EPO, which had a provision providing that J&J was authorized to sublicense to Roche the use of the Axel patents in the production of EPO for a royalty rate of 6.0%. However, the more established, and more reasonable, rate in light of all of Columbia's other licenses, is the 3.0% royalty rate for the sale of bulk products.

a. **Columbia's Damages For Roche's Inducing GI to Produce Bulk EPO**

Columbia is entitled to a reasonable royalty rate of 3.0% of the price of the bulk EPO sold by GI to Roche. However, the parties dispute whether Roche bought 133.69 grams of bulk EPO from GI or 241.237 grams. Columbia created a chart summarizing invoices of shipments from GI to Roche which stated that GI sold 241.237 grams of Bulk EPO to Roche at a cost of $39,758,300. Trial Ex. P267. However, Dr. Fouquet of Roche testified, without record support, that he thought that Roche received just over 130 grams of EPO from GI, but that an estimate of 162 grams seemed more plausible than 240 grams. Trial Tr. 1198-1200. Also, GI created its own chart summarizing its billing status with Roche in 1991, months after an injunction against GI was entered in the

Amgen case. This chart shows that GI shipped 133.69 grams of EPO to Roche at a cost of $26,737,540. Trial Ex. P76.

I find that a preponderance of the evidence suggests that GI shipped 241.237 grams of bulk EPO to Roche. Trial Ex. P267 summarized the invoices of shipments of bulk EPO from GI to Roche. Significantly, Roche did not object to whether Trial Ex. P267 summarized these invoices accurately. Instead, it argued that the invoices summarized by the chart did not accurately reflect the amount of bulk EPO shipped. However, although I gave Roche the opportunity at trial to provide evidence that the shipments described by the invoices were not received or accepted (see Trial Tr. 1194-1197), it failed to do so. As a result, I find that the invoices summarized by Trial Ex. P267 prove that GI shipped 241.237 grams of bulk EPO to Roche.

GI shipped this bulk EPO to Roche in Europe for a total sales price of $39,758,300. Taking a reasonable royalty rate of 3.0%, I find that Columbia is entitled to $1,192,749 in damages as a result of these sales.

b. Columbia's Damages For Roche's Shipping Albumin-Free EPO To GI

Roche is directly liable under 35 U.S.C. 271(g) for infringing the Axel patents by shipping albumin-free EPO to GI.

Neither Roche nor GI profited from this infringement. GI administered this albumin-free EPO to Jehovah's Witness patients as a "compassionate" treatment, and Roche received no revenue from GI as a result of the shipment. Trial Tr. 447-450. As a result, I find that this infringement entitles Columbia to only one dollar of nominal damages.

c. **Columbia's Damages For Roche's Return Of Bailed Cells Of GI's EPO Production Clone**

Roche is directly liable under 35 U.S.C. 271(g) for infringing the Axel patents by returning the bailed cells of the EPO production clone in 1989. However, Columbia has failed to prove that GI ever used these cells to make bulk EPO, and the cells have remained frozen since the Amgen injunction in 1991.[27] As a result, I find that Columbia is entitled to only one dollar of nominal damages as a result of this infringement.

IV. CONCLUSION

Because Columbia has proven that Roche has violated both 35 U.S.C. § 271(b) and 35 U.S.C. § 271(g), with respect to claim 54 and its dependent claims of the '216 patent, **JUDGMENT is hereby**

[27] Dr. Fritsch of GI's testimony was that he was uncertain whether these cells were ever used to make EPO. Trial Tr. 462-463.

ORDERED to issue in favor of Columbia in the amount of One Million, One Hundred Ninety-Two Thousand, Seven Hundred Fifty-One And 00/100 ($1,192,751.00) Dollars.

SO ORDERED.

Dated: September 30, 2002

NANCY GERTNER, U.S.D.J.